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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SUNG KIM, Individually and on behalf of all others similarly situated, Plaintiff, v. ALLAKOS INC., ROBERT ALEXANDER, LEO REDMOND, HENRIK RASMUSSEN, AND ADAM TOMASI, Defendants.	**Case No: 4:20-cv-01720-JSW** **AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Lead Plaintiff Sung Kim and Named Plaintiffs Christian Mayo and Allison Skye ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Allakos Inc. ("Allakos" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants who purchased the common stock of Allakos between March 14, 2019 and December 17, 2019, both dates inclusive (the "Class Period"), and held the stock until the end of the Class Period. Plaintiffs seek to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Allakos is a clinical stage biopharmaceutical company that has never generated any revenue. Allakos' business is focused on a single drug, AK002, which it is developing to treat eosinophil and mast related cell diseases. Accordingly, Allakos' business is entirely dependent on its ability to continue to raise money from investors until AK002 is approved by the U.S. Food and Drug Administration (the "FDA") and Allakos can commercialize the drug.

3. According to Allakos, the "lead indications" — diseases that AK002 is furthest along in the FDA approval process for — are eosinophilic gastritis ("EG") and eosinophilic gastroenteritis ("EGE"), which are inflammatory diseases of the stomach and small intestine. The current standard of care for those diseases is the use of steroids to decrease inflammation.

4. During 2018 and the first half of 2019, Allakos conducted a Phase 2 clinical trial that tested AK002 on EG and EGE patients for safety and effectiveness against those diseases, which the Company refers to as the "ENIGMA Trial." Given that EG and EGE are the lead indications for AK002, the ENIGMA Trial was the most important trial in Allakos' history.

5. On August 5, 2019, Defendants announced "positive" results for the ENIGMA Trial, and repeatedly emphasized that it was a "randomized, double-blind, placebo-controlled" clinical trial. Defendant Alexander, Allakos' CEO, told analysts that ENIGMA would be one of the two trials that Allakos intended to submit to the FDA when it tried to gain approval for the use of AK002 in EG and EGE patients in the future.

6. Allakos' stock shot up after the announcement and Defendants immediately capitalized. Mere hours after announcing the ENIGMA Trial results, Allakos announced that it was conducting a $200 million secondary offering of common stock, more than its $134.4 million July

2018 Initial Public Offering ("IPO"). The next day Allakos announced that it was upsizing its offering to $350 million and the Company ultimately raised $377.5 million in that secondary offering.

7. On December 18, 2019, Seligman Investments ("Seligman") issued an extensive research report about the ENGIMA Trial. Seligman, among other things, interviewed trial investigators who conducted the ENIGMA Trial for Allakos and reviewed and reprinted numerous posts that ENIGMA Trial participants and their families made to a private Facebook group. Seligman's research showed that Defendants had made numerous material misstatements and/or omissions about the ENIGMA Trial:

- Contrary to multiple statements in Allakos' public filings and how the vast majority of clinical trials are conducted, Allakos did not employ a third-party Contract Research Organization ("CRO") to conduct the ENIGMA Trial. Use of CROs is an important part of ensuring the integrity of clinical trials and Allakos' own trial investigators believed that the Company's failure to use one undermined the reliability of the ENIGMA Trial.
- Due to poor controls, including the failure to use a CRO, the blinding of the ENIGMA Trial was severely compromised for multiple reasons, including: (1) adverse reactions to infusions of AK002 made patients aware of whether they were receiving AK002 or placebo, (2) trial investigators told patients whether they believed they were getting the drug instead of a placebo, (3) patients were able to see their test results during the Trial, (4) patients were told they would qualify for an extension study if they did well in the trial, encouraging them to report symptom improvement, and (5) Allakos' executives had improper access to data and the patients during the Trial.
- Defendants understated the number of patients who used steroids during the ENIGMA Trial. Additionally, the dosages of steroids were inconsistent and left to the discretion of the trial investigators. This was a significant confounding factor in the Trial since steroids are the current standard of care for EG and EGE. The

administration of steroids may very well have been a cause of the positive results Allakos reported in the trial.

- Defendants falsely stated that there was only one drug-related serious adverse event during the ENIGMA Trial.
- Defendants falsely stated that patients did not experience the adverse effect of vomiting during the ENIGMA Trial.

8. All of these misstatements and/or omissions were highly material to investors because all of those issues will raise red flags with the FDA, making it less likely that Allakos will be able to use the ENIGMA Trial to gain approval of AK002 in the future. These misstatements and omissions also call into question the quality and integrity of the positive results Allakos reported for the ENIGMA Trial.

9. After Seligman issued its report, Allakos' stock dropped 17% from the closing price on December 17, 2019, over the next two days.

10. As a result of Defendants' knowing and/or reckless false and misleading statements and omissions concerning the ENIGMA Trial, the value of the price of Allakos common stock during the Class Period was artificially inflated. When Seligman's issuance of its report revealed the truth, Allakos' share price declined and Plaintiffs and other Class members suffered significant losses and damages.

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

12. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

13. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as Defendants conduct business and the Company is headquartered in this Judicial District.

14. In connection with the acts, conduct and other wrongs alleged in this Complaint,

Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

15. Lead Plaintiff, Sung Kim, as set forth in his previously filed certification incorporated by reference herein, purchased Allakos common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

16. Named Plaintiffs Christian Mayo and Allison Skye, as set forth in the certifications attached as Exhibit 1 to this Complaint, purchased Allakos common stock at artificially inflated prices during the Class Period and were damaged upon the revelation of the alleged corrective disclosure.

17. Defendant Allakos is a clinical stage biopharmaceutical company that focuses on developing the drug AK002. The Company is incorporated in Delaware and its principal executive offices are located at 975 Island Drive, Suite 201 Redwood City, California. Allakos common stock are traded on the NASDAQ ("NASDAQ") under the ticker symbol "ALLK."

18. Defendant Robert Alexander ("Alexander") has been the Company's Chief Executive Officer ("CEO") since April 2017 and a member of the its board of directors since May 2017. Defendant Alexander also served as President of the Company from November 29, 2017 until August 2019. Prior to becoming CEO of Allakos, Defendant Alexander served as CEO of another pharmaceutical company, ZS Pharma. He received a Ph.D. with a focus on immunology from the University of North Carolina.

19. Defendant Leo Redmond ("Redmond") has been the Company's Chief Financial Officer ("CFO") since August 1, 2019. Prior to joining Allakos, Defendant Redmond served as CFO and President of Presidio Pharmaceuticals.

20. Defendant Henrik Rasmussen ("Rasmussen") has been the Company's Chief Medical Officer ("CMO") since June 2017. Defendant Rasmussen previously served as CMO at three other pharmaceutical companies: ZS Pharma, Nabi Biopharmaceuticals, and Genvec. He also had held high level clinical positions at Novo Nordisk, British Biotech, and Pfizer. Defendant

Rasmussen has led numerous global drug development programs and regulatory filings worldwide, including New Drug Application submissions to the FDA. He received his Ph.D. and M.D. from the University of Copenhagen in Denmark and is trained in internal medicine and cardiology.

21. Defendant Adam Tomasi ("Tomasi") has served as the Company's Chief Operating Officer since April 2017, its President since August 2019, its Secretary since November 2017, and its CFO from April 2017 to August 2019. He previously served as Chief Scientific Officer and Head of Corporate Development at ZS Pharma. Defendant Tomasi received a Ph.D in Chemistry from the University of California Irvine and an MBA from the Massachusetts Institute of Technology.

22. Defendants Alexander, Redmond, Rasmussen, and Tomasi are sometimes referred to herein as the "Individual Defendants."

23. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

24. The Company is liable for the acts of the Individual Defendants and its employees under the doctrine of respondeat superior and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

25. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under respondeat superior and agency principles.

26. The Company and the Individual Defendants are referred to herein, collectively, as the "Defendants."

SUBSTANTIVE ALLEGATIONS

A. Allakos is Small Biotechnology Company Whose Prospects are Entirely Dependent of FDA Approval of a Single Drug, AK002.

27. Allakos was founded in March 2012 and became a public company through a July 2018 IPO that raised $134.4 million.

28. In the Company's Form 10-K for the fiscal year ended December 31, 2018, filed March 14, 2019 (the "2018 10-K") and Form 10-Q for the quarterly period ended March 31, 2019, filed on May 8, 2019 ("1Q 2019 10-Q"), Allakos described itself as entirely focused on the development of a single drug, AK002, stating "[w]e are a clinical stage biotechnology company developing AK002, our wholly owned monoclonal antibody, for the treatment of various eosinophil and mast cell related diseases. AK002 selectively targets both eosinophils and mast cells, white blood cells that are widely distributed in the body and play a central role in the inflammatory response." The Company further stated that it was "developing AK002 for the treatment of eosinophilic gastritis ('EG'), eosinophilic gastroenteritis ('EGE'), and eosinophilic esophagitis ('EoE')."

29. EG, EGE, and EoE are eosinophilic inflammatory diseases of the stomach, small intestine, and esophagus, respectively. The current standard of care for those diseases is the use of steroids to decrease the inflammation.

30. Although Allakos is also evaluating the use of AK002 in other medical conditions, obtaining FDA approval for the use of AK002 in EG, EGE, and/or EoE patients would be especially valuable to Allakos because AK002 has received orphan drug designation from the FDA for those diseases. An orphan drug designation is very valuable because it provides seven years of marketing exclusivity upon the approval of a drug intended to treat a rare condition. During that time, the FDA will not approve any other drug for the same indication unless it demonstrates clinical superiority.

31. All of Allakos' product candidates currently under development, other than AK002, are in preclinical development, meaning that they have not reached the state of development where the Company is testing the drug in clinical trials. Allakos previously conducted clinical trials for AK001, a compound similar to AK002, that was also supposed to treat eosinophil and mast cell related diseases, but the Company abandoned research on AK001 due to the drug's ineffectiveness.

32. In its 2018 10-K and 1Q 2019 10-Q, Allakos admitted its future prospects were entirely dependent on FDA approval of AK002: "Our future success is dependent on our ability to timely complete clinical trials and obtain marketing approval for, and then successfully commercialize AK002, our lead compound, for one or more indications…We are not permitted to market or promote AK002, or any other product candidates, before we receive marketing approval from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory authorities…."

33. As of December 31, 2018, Allakos had only 62 full-time employees, 40 of whom were engaged in research and development activities.

34. Allakos has never generated any revenue. In 2018, it had a net loss of $43.5 million and as of June 30, 2019 it had accumulated a deficit of $143.1 million since its founding.

B. The "ENIGMA Trial," a Purported Phase 2, Double-Blind, Placebo-Controlled Trial of AK002 in Patients with EG and/or EGE.

35. Drugs generally go through three phases of clinical trials prior to their approval by the FDA. In Phase 1 trials, the drug is administered to a small number of patients to test the drug's safety. If the drug is found to be safe enough, it can be tested in a Phase 2 trial. Phase 2 trials are conducted on larger groups of patients to continue to assess safety and to see if a drug is effective against a particular disease. Phase 3 trials generally enroll an even larger group of patients and focus on the effectiveness of the drug. The FDA generally requires a drug sponsor to demonstrate safety and efficacy in two adequate and well-controlled clinical trials to obtain marketing approval.

36. During 2018 and the first half of 2019, Allakos conducted a clinical trial it described in its 2018-10K as "a randomized, double-blind, placebo-controlled Phase 2 trial with AK002 in

approximately 60 patients with active, moderate to severe, biopsy-confirmed EG… and/or EGE."[1] Allakos further stated that the primary endpoint in the trial was "the reduction in gastric or duodenal eosinophils post-treatment" based on biopsies conducted on the patients. The secondary endpoint was "changes in EG and EGE patient symptoms, such as abdominal pain, nausea, vomiting and diarrhea, as reported by patients using Allakos' proprietary daily Patient Reported Outcome ("PRO") questionnaire." The Company refers to the trial as the "ENIGMA Trial."

37. A randomized, double-blind, placebo controlled trial is defined as a trial where neither the patients nor the researcher know who is getting the treatment being tested and who is getting the placebo. The purpose of a double-blinded study is to eliminate biased caused by the researchers and patients' expectations that the treatment will work.

38. Defendants Alexander and Rasmussen both discussed the ENIGMA Trial in a May 7, 2019 conference call with market analysts, both stating that the Company's "lead indication" for AK002 was EG and EGE. Accordingly, since the ENIGMA Trial was Allakos' first Phase 2 trial testing AK002 on EG and EGE patients, it was the most important clinical trial in the Company's history.

39. In the 2010 10-K and 1Q 2019 10-Q, which the Company issued on March 14, 2019 and May 8, 2019, respectively, explained that Allakos, like most small pharmaceutical companies, "do[es] not have the ability to independently conduct [its] clinical trials" and instead "currently rel[ies] on third-parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct [its] clinical trials of AK002 and expect to continue to rely upon third-parties to conduct additional clinical trials of AK002 and [its] other product candidates." The 2010 10-K and 1Q 2019 10-Q further warned that "[i]f we or any of our CROs fail to comply with applicable [Good Clinical Practice] requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA…or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications."

40. The use of an independent CRO to conduct clinical trials, such as the ENIGMA Trial, is the typical practice for all but the largest pharmaceutical companies because CROs play an

[1] 38% of the patients in the ENIGMA Trial also had EoE.

important role in making sure that clinical trials are carried out with integrity. Without the independent oversight of a CRO, there are numerous opportunities for a company sponsoring the trial to make changes during the trial and otherwise manipulate results to produce a better outcome for that company's drug. CROs operate under standard operating procedures which impose rules of Good Clinical Practice, such as Source Document Verification ("SDV"), database lock, and a prospectively defined statistical analysis plan ("SAP"). SDV, which is the comparison of reported trial data with information from primary health records of trial subjects, is an important component of ensuring the integrity of trial data. Database lock is the crucial practice of finalizing the database of trial data to prevent unauthorized or unintentional changes. Database lock is extremely important in randomized blinded trials since the database must be locked before the blind of the doctors and patients is broken to protect the integrity of the trial. Setting up an SAP prior to the trial protects the integrity of a clinical trial because it stops the company conducting the clinical trial from altering the statistical methodology mid-trial to obtain a more favorable result.

41. CROs also often have levels of expertise to pressure test the trial's integrity by challenging the study design, filtering out study biases, selecting the endpoints, defining the analysis approaches, and interacting on behalf of the sponsor with FDA. The absence of a CRO would be a red flag to encourage FDA to investigate whether a trial adhered to Good Clinical Practice. If the FDA believes that a trial did not follow Good Clinical Practice, it is less likely that a sponsor can use the trial to gain FDA approval for a drug.

C. On August 5, 2019, Allakos Announced "Positive" Results From the ENIGMA Trial on the Same Day that it Announced a Secondary Offering of Stock.

42. On August 5, 2019, Allakos issued a Form 8-K signed by Defendant Alexander that attached a press release entitled "Allakos Announces AK002 Met All Prespecified Primary and Secondary Endpoints in Phase 2 Randomized, Double-Blind, Placebo-Controlled Study in Patients with Eosinophilic Gastritis (EG) and/or Eosinophilic Gastroenteritis (EGE)," which touted the "positive results" of the "randomized, double-blind, placebo-controlled" ENIGMA Trial (The "August 5, 2019 ENIGMA Press Release").

43. The August 5, 2019 ENIGMA Press Release further stated that there was only "1

drug-related serious adverse event (SAE) in the [ENIGMA Trial], consisting of an infusion-related reaction which recovered within 24 hours" and that "[s]tatistically significant results were also observed on all primary and secondary endpoints in the subgroup of patients who did not receive steroids."

44. On August 5, 2019, Allakos also hosted a conference call for analysts discussing the results of the ENIGMA Trial (the "August 5, 2019 Conference Call") and the Company issued a Form 8-K signed by Defendant Alexander on the same date with a presentation entitled "Phase 2 Eosinophil Gastritis and Gastroenteritis Study Results." Defendants Alexander and Rasmussen used that presentation during the August 5, 2019 Conference Call (the "August 5, 2019 Presentation," attached as Exhibit 2).

45. On the August 5, 2019 Conference Call, Defendant Alexander touted the results of the ENGIMA Trial and specifically reminded analysts that it was a "randomized, double-blind, placebo-controlled study." Defendant Alexander further stated that the ENIGMA Trial is one of two trials that Allakos would use to try to gain FDA approval for the use of AK002 in EG and EGE patients.[2]

46. Defendants Alexander and Rasmussen also delved deeper into certain aspects of the ENIGMA Trial on the August 5, 2019 Conference Call.

47. Regarding the use of steroids in the ENIGMA Trial, Defendant Rasmussen stated that the study's "protocol allowed low dose chronic background steroids as long as the patients were still symptomatic, as long as the patient still met the eosinophil inclusion criteria and as long as steroid had to be keep [sic] constant throughout the screening period as well as the study." He further stated that "Acute steroid use was allowed per site discretion as a premedication before infusion [of AK002] as a single dose of steroid to reduce the incidence of infusion-related reactions [as] well as therapeutically to manage infusion-related reactions if they did occur." Rasmussen represented that the acute steroids use was well balanced between groups (28% on AK002 versus 35% on placebo) and stated that "looking at analysis excluding all patients on steroids, we are

[2] Allakos intends the second trial to be a Phase 3 trial that it has not conducted yet.

getting the same compelling efficacy data." Additionally, Slide 24 of the August 5, 2019 Presentation represented that only 11 out of 39 members of the group that received AK002 and completed the Trial[3] were also treated with any steroids at all.

48. Defendant Rasmussen also specifically confirmed that the ENIGMA trial had only one drug related serious adverse event — an infusion reaction that was resolved within 24 hours.

49. An analyst asked Defendant Alexander about Slide 20 of the August 5, 2019 Presentation, which showed a "100%" reduction in vomiting in the group treated with AK002. Defendant Alexander represented that vomiting was "not as frequent as [other symptoms] and "not as severe."

50. Mere hours after announcing the results of the ENIGMA Trial, Allakos announced a secondary public offering of $200 million of shares in its common stock and filed a Form S-3 registration statement, signed by Defendants Alexander and Redmond, and a preliminary prospectus supplement that continued to tout the ENIGMA Trial.

51. Allakos also issued its Form 10-Q for the quarterly period ended June 30, 2019, on August 5, 2019 ("2Q 2019 10-Q"). The 2Q 2019 10-Q stated, like the 2010 10-K and 1Q 2019 10-Q did, that Allakos, does not have the ability to independently conduct its clinical trials and relies on third-parties, such as CROs, to conduct its clinical trials for AK002.

D. Defendants Capitalize Immediately on their Statements About the ENIGMA Trial by Almost Doubling the Value of Their Secondary Offering and Granting Stock Options to Defendant Redmond that had Already Almost Tripled in Value.

52. Defendants' statements concerning the ENIGMA Trial caused Allakos' stock to almost triple from its closing price of $31 on Friday, August 2, 2019 to a closing price of $87.5 on August 7, 2019.

53. On the evening of August 6, 2019, Allakos announced it was upsizing its secondary offering of common stock to $350 million at an offering price of $77 per share. The Company filed its final prospectus supplement for its offering on August 7, 2019. On August 9, 2019, the Company announced it had raised $377.5 million.

[3] Four other patients who received AK002 did not complete the Trial.

54. On August 6, 2019, Allakos also filed a Form 4 stating that it had granted 120,000 stock options to Defendant Redmond on August 2, 2019 at a price of $31. Since Allakos' stock closed at $79.47 on August 6, 2019, by the time Allakos announced the options grant, Redmond's options were already worth almost $6 million.

E. On December 18, 2019, Seligman Investments Issued a Detailed Report Showing That Defendants Had Made Numerous Misstatements About the ENIGMA Trial.

55. On December 18, 2019, Seligman issued a report entitled "A Suspect Biotech with a Phase 2 Farce, Incredulous Trial Investigators, and Warning Signs of Potential Fraud" (the "Seligman Report," attached as Exhibit 3). Seligman manages long-only and long/short equity strategies and occasionally publishes research reports based on intensive, deep-dive fundamental research.[4]

56. The Seligman Report is the result of extensive research by Seligman into Allakos and the ENIGMA Trial. Seligman interviewed four people who served as Trial Investigators for the ENIGMA Trial. During a clinical trial, the drug is dispensed under the immediate direction of the Trial Investigators. Accordingly, the Trial Investigators had first-hand knowledge of what occurred during the ENIGMA Trial.

57. Seligman also reviewed the private Facebook group for EG, which contained hundreds of posts by ENIGMA Trial participants and their families. Seligman believes that most of the 65 participants in the ENIGMA Trial are members of the EG Facebook group.

1. Contrary to Numerous Statements in its Public Filings, Allakos Did Not Use a CRO When it Conducted the ENIGMA Trial.

58. Seligman confirmed with four different ENIGMA Trial investigators that Allakos did not use a CRO to conduct the ENIGMA Trial. According to Seligman's research, more than 90% of clinical trials employ a CRO. The trial investigators that Seligman interviewed confirmed that Allakos' failure to use a CRO was highly unusual and said that they had never been involved in another clinical trial that did not use a CRO.

59. The First Trial Investigator that Seligman spoke with initially believed that he was

[4] Seligman is an affiliate of Columbia Threadneedle Investments group, an asset manager overseeing $476 billion of client assets.

interacting with employees of a CRO during the ENIGMA Trial, and was struck by how aggressively they behaved. Because of that, he asked them what company they worked with and they said they were employees of Allakos. He was surprised because he had never seen a biotech company conduct a clinical trial without a CRO before. He said that "[Allakos] was actively involved during the trial" and "aggressive." He added that "[t]hese guys are businesspeople. They think we made a couple hundred million and this could be one of these."

60. Seligman spoke with a Second Trial Investigator, who also initially assumed that Allakos used a CRO. Seligman asked him to verify that he had been working with a CRO. When the Second Trial Investigator asked his staff and confirmed that he had actually been working with Allakos employees, he was shocked. He stated: "We always deal with a third party CRO that makes sure there's compliance with internal and external protocols and inclusion/exclusion criteria." The Second Trial Investigator further explained that "***[i]t should be a third party to prevent bias.*** I don't know why they didn't use a third party. ***I'd say 95% of time it's a third party. It's never the company. We've conducted so many trials. It's never been the company. It's one of the biases that you definitely want to remove.*** Inherent bias from internal review shouldn't exist in these trials. ***This would be a huge red flag in phase three and the FDA wouldn't like it. They would be stupid to have their own people do compliance, assessment, and auditing. It just won't fly with the FDA.***" (emphasis added). The Second Trial Investigator added that he had probably done 20 trials in the past five years and all twenty used a third party CRO because "[t]hat's standard operating procedure" and its "the right thing to do. I was shocked to see that Allakos served as their own CRO."

61. The Third Trial Investigator that Seligman interviewed, like the first two, had assumed that he was working with a CRO. After he confirmed with his facility's clinical research coordinator that the person who visited the trial site was an employee of Allakos, not a CRO, he told Seligman: "I believe the site monitors were employees of Allakos. I just asked my clinical research coordinator. ***The person who came for site visits is an Allakos employee. My patient coordinator worked directly with Allakos. If it was an Allakos person and not a CRO I'd be very bothered by that. It wouldn't be honest.***" (emphasis added).

62. Finally, Seligman interviewed a Fourth Trial Investigator, who appeared to know all along that Allakos conducted the ENIGMA Trial without a CRO, but he did not know why the Company chose that route. He said that for Allakos to run the Trial properly some employees would need to be blinded and others unblinded. Given the size of Allakos — the Company had only 40 employees who were engaged in research and development activities as of the end of 2018 — it would have been very difficult for it to maintain the necessary firewall between employees to maintain the blinding of the ENIGMA Trial even if the Company made an honest attempt to do so. Unsurprisingly, as discussed in the next section, the blinding of the ENIGMA Trial was severely compromised in numerous ways, including because Defendant Rasmussen had improper contact with a patient and because Allakos had improper access to interim data from the Trial.

63. Given that Allakos' failure to use a CRO and aggressive behavior during the ENIGMA Trial raised troubling questions, Seligman looked into whether the biopsies done for the Trial were sent to the Company or a panel of independent, third party pathologists for analysis, given the well-known issues around bias and subjectivity in biopsy measurements. One of the trial investigators for the ENGIMA Trial told Seligman that all the biopsies were sent to one person who had ties to Allakos. Based on reviewing abstracts from the pathology lab, Seligman determined that the reader was either Diane S. Lidke or Tracy I. George. In an article entitled "Variability of PD-LI Expression in Mastocytosis" published in the February 13, 2018 issue of the journal *Blood Advances*, Lidke and George both disclosed that they received research funding from Allakos.

64. In addition to failing to use a CRO and using a single reader with a conflict of interest for the ENGIMA Trial, Allakos' clinical staff is rife with nepotism. Defendant Rasmussen's son, Jacob Rasmussen, and daughter, Camilla Shaw, are VP of Clinical Operations[5] and a Clinical Program Manager, respectively. Accordingly to the Seligman Report, VP of Clinical Operations is likely the number two clinical role at Allakos after his father's role. Shaw holds her role even though she is the only Allakos employee located in Utah and she graduated from college in 2012.

[5] According to Allakos' Proxy Statement filed on April 30, 2019, Jacob Rasmussen's position was Clinical Program Manager, but Seligman stated that based on its research, it believed that Jacob Rasmussen has either been promoted or the disclosure was wrong. Allakos' Proxy Statement filed on April 15, 2020, stated that Jacob Rasmussen was Senior Direct of Clinical Project Management.

Defendant Rasmussen and his son also, notably, hold their roles even though they are located in Maryland, whereas virtually all other Allakos employees are located in the San Francisco area. As of the issuance of the Seligman Report, Allakos had granted Defendant Rasmussen's children stock options worth approximately $13 million.

2. Poor Controls Greatly Compromised the Blinding of the ENIGMA Trial — Purportedly Randomized and Double-blind — Rendering the Patient Reported Outcome Score Unreliable

65. Defendants told investors repeatedly that the ENIGMA Trial was a "randomized, double-blind, placebo-controlled" trial, but, unsurprisingly given Allakos' failure to use a CRO and its admission that it does not have the ability to independently conduct its clinical trials, the ENIGMA Trial had poor controls that greatly compromised its blinding. According to the ENIGMA Trial Investigators and posts on the EG Facebook group, the blinding was compromised because (1) adverse reactions to infusions of AK002 made patients aware of whether they were receiving AK002 or placebo, (2) trial investigators told patients whether they believed they were getting the drug instead of a placebo, (3) patients were able to see their test results during the Trial, (4) patients were told they would qualify for an extension study if they did well in the trial, encouraging them to report symptom improvement, and (5) Allakos had improper access to data and the patients during the Trial.

66. *First*, because AK002 causes a significant reaction in many patients when infused, three of the ENIGMA Trial Investigators that Seligman spoke with expressed concern that the entire Trial was unblinded because reactions to AK002 tipped the patients off about whether they were receiving AK002 or the placebo.

67. The EG Facebook group shows that the trial investigators' fears were warranted — the Seligman Report includes eight Facebook posts in which patients speculated that they were receiving AK002 because they had a reaction to the infusion or that they were not because they did not have a reaction.

68. *Second*, five patients or their family members posted that the *trial investigators themselves* told the patients they were likely getting the drug. The posts stated:

- The symptoms I had: shortness of breat [sic], flushing, chest tightness are

> very typical generalized transfusion reactions. However with how quickly they happened and that I was able to restart the transfusion without continued reactions the doctors believe it's from the large amount of eosinophis going through lysis so quickly…
>
> - The dr is convinced she got the drug and since she has so many [eosinophis], her reaction was due to a large kill off of [eosinophis].
> - My daughter had a severe reaction 2 hours after the start of the first infusion. The dr thinks she is definitely getting the drug.
> - Since the dr thinks she was getting the drug all along, it may be no different.
> - Her 1st infusion was a "horrific reaction" and the dr firmly believes she did get the drug…

69. *Third*, remarkably, one patient in the ENIGMA Trial posted on Facebook that it was "so great" that he or she was "able to see the test results, biopsies, bloodwork while on the drug." Additionally, seven patients posted that they received endoscopy results during the trial, including one that stated that "clinically and by endoscopy we all should have a clear indication if we are getting the drug or placebo."

70. Control problems that tip patients off about whether they are receiving the drug or a placebo are red flags for the FDA that create doubt as to the integrity of the trial and its results. In the FDA's Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, issued in December 2009, the FDA warned that unblinding due to treatment reaction was a serious concern for the FDA when it reviewed Patient Reported Outcomes: "In blinded clinical trials, patients should be blinded to treatment assignment throughout the trial. If the treatment has obvious effects, such as adverse events, the clinical trial may be at risk for unintentional unblinding…. ***Suspicion of inadvertent unblinding can be a problematic review consideration for the FDA when assessing PRO endpoints***." (emphasis added).

71. *Fourth*, the Patient Reported Outcome scores of patients were also biased by the fact that, according to posts on the EG Facebook group, patients in the ENIGMA Trial were informed that if they had success in the ENIGMA Trial, they would be accepted into the extension study

where they would be guaranteed to receive the drug and avoid placebo. This provided patients with an improper incentive to report improvement in the Patient Reported Outcome surveys.

72. *Fifth*, posts to the EG Facebook group also showed that a patient's parent had direct contact with Defendant Rasmussen. Seligman told one of the trial investigators they spoke to about this and the investigator found it very concerning for the integrity of the trial:

> If Rasmussen talked to a patient's parent, that's what I mean when I say they were heavily involved. That's unusual. It seems a little weird to me. The company should be blinded to the patient's name. It doesn't make any sense. The patient's ID is a private matter. Patients are desperate. Parents sometimes call the company. It's a gray area. Once a patient identifies themselves to the company, it's a HIPAA violation. It's concerning to some degree. He could be influencing them. Randomization should be done by investigational pharmacist at each site. It's unusual and is a little concerning.

73. Additionally, two patients or family members of patients posted to the EG Facebook group that they were told that Allakos was discontinuing the lowest (.3mg dose) of AK002 mid-trial because it was ineffective. One of the posts stated that a research coordinator told them that. This shows that Allakos had access to the data during the ENIGMA trial and was, therefore, improperly unblinded. Accordingly, this was a violation of Good Clinical Practices and a red flag for the FDA.

3. Defendants Misrepresented the Use of Steroids During the ENIGMA Trial.

74. The August 5, 2019 Presentation stated that only 11 of the 39 patients (28%) who received AK002 during the ENIGMA Trial and completed the Trial also received any steroids. Furthermore, during the August 5, 2019 Conference Call, Defendant Alexander flatly asserted "[i]n terms of the steroid, I mean, it had absolutely 0 effect on the results, and that was shown in the study. So the idea that steroids are confounding the results is specious."

75. According to Seligman's interviews with trial investigators for the ENIGMA Trial, it was not plausible that only 28% of the patients given AK002 also received steroids. The trial investigators told Seligman that 80% of EG and EGE patients are typically on steroid therapy. Additionally, two of the investigators indicated that it was completely at their discretion whether to put patients on steroids. One of the trial investigators said ***he gave all of his patients 20 mg of prednisone (a powerful steroid)*** prior to the first two infusions. Another said he only put some patients on steroids, but said he used ***80mg of prednisone***.

76. Defendants misstatements about the number of patients on steroids was highly material since steroids are the current standard of care for EG and EGE and highly effective against those diseases. For example, the study "Successful Treatment of Eosinophilic Gastroenteritis with Clarithromycin," which appeared in the December 2012 issue of the *Korean Journal of Internal Medicine*, stated that 90% of EGE patients respond to steroid therapy and even 5 mg a day could suppress symptoms.

77. The FDA's February 2019 Draft Guidance on EoE, a closely related disease to EG and EGE,[6] specifically warned about the importance of steroid controls during clinical trials. Accordingly, widespread steroid use in the ENIGMA Trial will be a red flag for the FDA when it evaluates the trial. Furthermore, one of Allakos' own trial investigators told Seligman that he believed steroids could be a confounding factor, stating "[c]ould steroids be a confounding factor here? Of course. With 80mg of prednisone, one shot can give you an acute effect."

78. Notably, accordingly to Facebook posts by family members of participants in the extension study following the ENGIMA Trial, Allakos added 80 mg of prednisone to the AK002 infusion protocol along with another steroid, Medrol, that is even stronger. The family members of the patients posted:

- I am still not sure why it was necessary to be cautious enough today that necessitated her to have 80 mgs [of prednisone] and then also include her medrol during the infusion today. The data that has come in must have shown it is necessary to avoid reaction. After all that is what the trial is for. There must have been reactions as the dose went up without predosing with prednisone. They just told us it was a new protocol to be given 80mgs prior to the infusion. In open label infusions here on.

- She was predosed with 80 mg of prednisone yesterday that has been a [sic] added protocol to the open label infusions along with getting Medrol during the infusion.

If it was actually true that only 11 of the 39 patients who received AK002 and completed the ENIGMA Trial also received steroids and AK002 was effective without steroids, as Defendants claimed, there would have been no reason for Allakos to mandate steroids as part of the protocol for

[6] There is no FDA Guidance specifically for EG or EGE.

the extension study. The fact that Allakos did mandate pre-infusion steroids during the extension study strongly suggests that either more than 11 of the 39 AK002 patients in the ENIGMA study received them or that the no steroid group did not perform as well as Defendants contend.

79. In an analyst report on Allakos published on March 25, 2020, entitled "Phase 3 EGID Program Update Leaves Many Unanswered Questions – Reiterate Underperform," SMBC Nikko Securities America, Inc. rated Allakos' common stock as an underperform "[s]ince we still do not know the mean cumulative steroid doses received by [AK002] vs. placebo arms from the [Phase 2] ENIGMA trial, all of the confounding risk remains in [Phase 3]." The analyst report also indicated that Allakos' Phase 3 trial for EG and EGE would have a premedication regimen of prednisone before the first dose of AK002 and that investigators would be free to use steroids to manage infusion reactions, which (as with the steroid protocol in the ENIGMA extension study) is inexplicable if it is actually true that so few patients in the ENIGMA Trial received steroids and patients who did not receive steroids performed as well as Allakos claims. Regarding Allakos' decision to give prednisone, the analyst report stated that "it remains entirely possible that steroids are driving the majority of symptom benefits, which coincidentally occur together with the first dose of [AK002] when steroids are most likely to be given."

4. Defendants Misrepresented that There was Only One Drug-Related Serious Adverse Event During the ENIGMA Trial.

80. The FDA's Guidance for Industry and Investigators — Safety Reporting Requirements for Investigational New Drug and Bioavailability/Bioequivalence Studies, issued in December 2012, and 21 CFR 312.32(a) state that

> ***An adverse event or suspected adverse reaction is considered "serious" if***, in the view of either the investigator or sponsor, ***it results in any of the following outcomes:*** Death, a life-threatening adverse event, ***inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions***, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

81. Defendants stated that there was only one drug-related serious adverse event, which

resolved itself within 24 hours, and no adverse events outside the infusion windows in the ENIGMA Trial. Defendants also stated that 9% of the AK002 patients and 14% of the placebo patients had "treatment emergent serious adverse event[s]" during the ENIGMA Trial. A treatment emergent serious adverse event is an event that emerges during treatment having been absent pre-treatment, or worsens relative to the pre-treatment state. When asked about these serious adverse events during the August 5, 2019 Conference Call, Defendant Rasmussen indicated that they were not drug related, i.e. unrelated to AK002 and, instead, had to do with the general health problems of the ENIGMA Trial patient population:

> This is a sick patient population who have a lot of problems. Many of them have a number of concomitant diseases. So typically, the serious adverse events were basically defined by a patient being hospitalized, in most cases, because of GI problems. And that's probably why the incidence was slightly higher on placebo as compared to on active.
>
> So we had a couple of patients who were hospitalized because of severe abdominal pain and/or dehydration, which of course, is a common problem with these patients. So nothing remarkable, but mostly GI-related. We did have one patient who had mental confusion, and turned out that she was on background drugs. So that kind of stuff.

82. The claim that only one of the serious adverse events in the ENIGMA Trial was drug-related was flatly contradicted by posts by ENIGMA Trial patients on the EG Facebook group that the Seligman Report reprinted. The posts from patients and their family members show that there were multiple serious adverse events that directly resulted from infusions of AK002:

- Getting admitted after infusion #3 of AK002 [because of low oxygen]. Had a reaction….
- Please join me in say a prayer tonight for one of our brave members, [redacted],who is participating in the AK002/Siglec8 trial and had a significant reaction to her 3rd infusion. She is still in the hospital having symptoms of low [oxygen].
- I had to be pulled off the study as it's my third admission since my admission following my infusion in March. I didn't have to be admitted until later in the month in April with high lactate and pneumonia then my May infusion caused horrible stomach pain and a week unable to eat or drink without severe pain. I wasn't discharged because my symptoms resolved but because insurance wouldn't pay any longer.

- Had the same reaction I've had every time – severe nausea, headache and super severe stomach pain.

- Her first infusion was a "horrific reaction" and dr firmly believes she did get the drug.

- After two iron infusions and an AK002 infusion over the past week…at the ER at 3 am with [redacted] who has had a migraine since last Wednesday. (Literally with no break). She just can't take it anymore.

83. Notably, there are also Facebook posts discussing patients getting severe ocular migraines (migraines that often cause vision loss or blindness) multiple times a day from AK002 infusions and reporting it to trial investigators:

- [Redacted] is heading to [redacted] in the morning for her 4th infusion of AK002. Hopefully, it will go off without incident. She is getting multiple visual migraines where her pheripheral [sic] eyesight is lost n [sic] then gets a bad headache. She's had multiple episodes over the last month n [sic] 3 today. I am wondering if this could be a side effect of the AK002. She usually gets maybe 1 a year. ***Will discuss it with the Doctor.*** Oh so many things to always worry about.

- Please report this to your research physician. Dr [redacted] was very concerned [redacted] had 7 full blown ocular migraines this past month. She is reporting it as a possible adverse side effect….She lost her vision 2 separate times yesterday.

(emphasis added).

84. Serious adverse events are a very important consideration for the FDA when evaluating trials. Both 21 CFR 312.32(c) and the FDA's Guidance on Safety Reporting Requirements for Investigational New Drug and Bioavailability/Bioequivalence Studies require sponsors of clinical trials to report serious adverse events to the FDA.

5. Defendants Falsely Stated That Patients in ENGIMA Trial Did Not Experience Vomiting.

85. Allakos reported that patients did not report any vomiting during the ENGIMA Trial on their Patient Report Outcome surveys and it did not list vomiting as one of AK002's adverse effects.

86. One of the ENIGMA Trial investigators that Seligman interviewed expressly stated that Defendants' statements about vomiting were false:

> Page 20 of their slide presentation says zero vomiting. Vomiting is a huge symptom. Most patients have vomiting. N=39 in the active arms and no vomiting. How did they find 39 patients without vomiting? ***To me the biggest concern is the vomiting thing. Maybe they made a mistake. It doesn't make any sense.***

(emphasis added).

87. Facebook posts by participants in the ENIGMA Trial and their families strongly support that trial investigator's statement. They show that participants in the ENIGMA Trial experienced a significant amount of vomiting, and it was worse than it was prior to their participation in the ENGIMA Trial:

- [Redacted] has kept the daily journal for a week now for clinical symptoms. She is vomiting with gastric pain n [sic] nausea almost everyday.
- I've recently added nightly vomiting to my normal EG routine that used to consist of "just" severe diarrhea and horrible abdominal and chest pain and trouble swallowing….
- Anyone on the Ak002 trial get EXTREMELY ill the day after. Since 2am I've been vomiting non-stop, dizzy, blurred vision, high heart rate. Just wondering if this has happened to anyone else?
- Anyway, I am concerned and sad that she has thrown up a few times over the last few weeks…She is very nauseous too….She just mentioned she threw up with absolutely no emotion and, of course, I almost lost my mind. I said "What?? You Threw up?"

88. Additionally, under FDA Guidance and 21 CFR 312.32(a)-(b), Allakos was required to report to the FDA, as adverse events, all medical conditions that worsened while on the study treatment. Based on the statements of patients in the ENGIMA Trial and their families, vomiting clearly qualified under this rule.

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

A. Material Misstatements About Using a CRO to Conduct Clinical Trials.

89. On March 14, 2019, Allakos issued the 2018 10-K, which was signed by Defendants Alexander and Tomasi. Additionally, attached to the 2018 10-K were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), signed by Defendants Alexander and Tomasi, attesting that

"this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" and that they have disclosed all fraud.

90. On May 8, 2019, Allakos issued its 1Q 2019 10-Q, signed by Defendants Alexander and Tomasi. Additionally, attached to the 1Q 2019 10-Q were certifications pursuant to SOX, signed by Defendants Alexander and Tomasi, attesting that "this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" and that they have disclosed all fraud.

91. On August 5, 2019, Allakos issued its 2Q 2019 10-Q, which was signed by Defendants Alexander and Redmond. Additionally, attached to the 2Q 2019 10-Q were certifications pursuant to SOX, signed by Defendants Alexander and Redmond, attesting that "this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" and that they have disclosed all fraud.

92. On August 5, 2019, the Company filed a Form S-3 registration statement, signed by Defendants Alexander and Redmond. That registration statement incorporated the 2018 10-K, 1Q 2019 10-Q, and 2Q 2019 10-Q.

93. On November 12, 2019, Allakos issued its Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 (the "3Q 2019 10-Q"), which was signed by Defendants Alexander and Redmond. Additionally, attached to the 3Q 2019 10-Q were certifications pursuant to SOX, signed by Defendants Alexander and Redmond, attesting that "this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" and that they have disclosed all fraud.

94. The 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, and 3Q 2019 10-Q all contained

identical statements that Allakos does not have the ability to independently conduct clinical trials, and therefore it relies on third-parties, such as CROs, to conduct its clinical trials for AK002:

> ***We rely on third-parties to conduct our clinical trials and those third-parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.***
>
> ***We do not have the ability to independently conduct our clinical trials. We currently rely on third-parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials of AK002 and expect to continue to rely upon third-parties to conduct additional clinical trials of AK002 and our other product candidates. Third-parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data.*** These third-parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third-party will devote to our clinical trials. Some of these third-parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our drug development activities.

(emphasis in first three lines in original; other emphasis added).

95. The bold and italicized portion of the foregoing statements was materially false and misleading because Allakos did not use an independent CRO for the ENIGMA Trial. Instead, the Allakos was aggressively involved in trial and used a single reader who had financial ties to Allakos to read tissue samples. By misrepresenting and/or failing to disclose these facts, Allakos misled investors about the integrity and quality of the ENIGMA Trial results and about the likelihood that Allakos will be able to use the ENIGMA Trial to gain FDA approval of AK002.

B. Misstatements that the ENIGMA Trial was a Randomized, Double-blind, Placebo-Controlled Trial.

96. Defendants repeatedly told investors that the ENIGMA Trial was a "randomized, double-blind, placebo-controlled" trial.

97. On March 14, 2019, Allakos issued the 2018 10-K, which was signed by Defendants Alexander and Tomasi. Additionally, attached to the 2018 10-K were certifications pursuant to SOX, signed by Defendants Alexander and Tomasi, attesting that "this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with

respect to the period covered by this report" and that they have disclosed all fraud. The 2018 10-K was also incorporated by reference into the Form S-3 registration statement, signed by Defendants Alexander and Redmond, and filed by the Company on August 5, 2019.

98. The 2018 10-K referred to the ENIGMA trial as a "randomized, double-blind, placebo controlled" trial: "***We have initiated a randomized, double-blind, placebo-controlled Phase 2 trial with AK002*** in approximately 60 patients with active, moderate to severe, biopsy-confirmed EG (stomach >30 eosinophils/hpf in 5 hpf) and/or EGE (duodenum >30 eosinophils/hpf in 3 hpf)."

99. On August 5, 2019, Allakos issued a Form 8-K signed by Defendant Alexander with the August 5, 2019 ENIGMA Press Release attached. The August 5, 2019 ENIGMA Press Release was also incorporated by reference into the Form S-3 registration statement, signed by Defendants Alexander and Redmond, and filed by the Company on August 5, 2019.

100. The August 5, 2019 ENIGMA Press Release stated:

> REDWOOD CITY, Calif., Aug. 05, 2019 (GLOBE NEWSWIRE) -- ***Allakos Inc. (the "Company") (Nasdaq: ALLK) today announced positive results from its Phase 2 randomized, double-blind, placebo-controlled trial of AK002 in patients with eosinophilic gastritis and/or eosinophilic gastroenteritis.*** All AK002 dose arms showed clinically meaningful and statistically significant benefits compared to placebo on all prespecified primary and secondary endpoints, including gastrointestinal tissue eosinophil counts and patient reported disease symptoms. Statistically significant differences in patient symptoms between the active and placebo groups occurred one day following AK002 administration…
>
> **Phase 2 ENIGMA Study Design**
>
> ***This randomized, double-blind, placebo-controlled Phase 2 trial of AK002*** enrolled patients with active, biopsy-confirmed EG and/or EGE. Patients were required to be moderately to severely symptomatic based on a patient reported symptom questionnaire and have biopsy confirmed eosinophilia of the stomach (≥30 eosinophils/HPF in 5 HPFs) and/or duodenum (≥30 eosinophils/HPF in 3 HPFs)…

(Emphasis in original for "Phase 2 ENIGMA Study Design"; other emphasis added).

101. On August 5, 2019, Allakos conducted the August 5, 2019 Conference Call and the Company issued a Form 8-K signed by Defendant Alexander on the same date with the August 5,

2019 Presentation attached. Defendants Alexander and Rasmussen used the August 5, 2019 Presentation during the August 5, 2019 Conference Call. The Form 8-K with the August 5, 2019 Presentation attached was incorporated by reference into the Form S-3 registration statement, signed by Defendants Alexander and Redmond, and filed by the Company on August 5, 2019.

102. Defendant Alexander stated during the August 5, 2019 Conference call that "[t]he AK002 met all pre-specified primary and secondary endpoints in our study. And those are in patients with gastritis, gastroenteritis as well as concomitant EoE. In terms of our primary and 2 key secondary endpoints, we saw a tremendous effect on all of them. ***And a reminder, this was a randomized, double-blind, placebo-controlled study.***" (emphasis added).

103. Defendant Rasmussen stated during the August 5, 2019 Conference Call that: "So basically, the study design of ***the ENIGMA study was randomized, double-blind, placebo-controlled study*** in patients with eosinophilic gastritis and/or gastroenteritis." (emphasis added).

104. Slides 5, 12, and 40 of the August 5, 2019 Presentation stated that the ENIGMA Trial was a "***Randomized, double-blind, placebo-controlled study***." (emphasis added).

105. Allakos filed a preliminary prospectus supplement on August 5, 2019 and a final prospectus supplement on August 7, 2019, both of which formed part of the Form S-3 registration statement filed by Allakos on August 5, 2019 and signed by Defendants Alexander and Redmond.

106. That preliminary prospectus supplement and final prospectus supplement stated:

> ***We recently reported data from a randomized, double-blind, placebo-controlled phase 2 trial of AK002 in patients with active, biopsy-confirmed EG and/or EGE.*** 38% of the patients in the study also had EoE, allowing us to evaluate the effects of AK002 on EoE. All AK002 dose arms showed clinically meaningful and statistically significant benefit compared to placebo on all prespecified primary and secondary endpoints, including gastrointestinal tissue eosinophil counts and patient reported disease symptoms….
>
> ***Phase 2 ENIGMA Study Design***
>
> ***The randomized, double-blind, placebo-controlled phase 2 trial of AK002 enrolled patients*** with active, biopsy-confirmed EG and/or EGE.

(Emphasis in original for "Phase 2 ENIGMA Study Design"; other emphasis added).

107. The bold and italicized portions of the statements in Paragraphs 98, 100, 102-104,

and 106 are false and misleading because the ENIGMA Trial was not well controlled and the blinding was compromised. Defendants failed to disclose that Allakos conducted the ENIGMA Trial without an independent CRO, which is typical industry practice for maintaining proper controls and Good Clinical Practice in clinical trials. Additionally, the blinding of the ENIGMA Trial was severely compromised because: (1) infusion reactions made patients aware of whether they were receiving AK002 or the placebo; (2) the trial investigators told patients in the treatment group of the trial that they were likely getting the drug instead of the placebo; (3) patients were able to see their endoscopy results during the Trial; (4) patients in the Trial were told that if they had success in the Trial, they would qualify for an extension study in which they were sure to get the drug and avoid the placebo; and (5) Allakos had improper access to data and the patients during the Trial. By misrepresenting and/or failing to disclose these facts, Allakos misled investors about the reliability of the Patient Reported Outcomes from the ENIGMA Trial and about the likelihood that Allakos will be able to use the ENIGMA Trial to gain FDA approval of AK002.

C. Misstatements Concerning Steroid Use in the ENIGMA Trial.

108. On August 5, 2019, Allakos issued a Form 8-K signed by Defendant Alexander with the August 5, 2019 ENIGMA Press Release attached.

109. Allakos filed a preliminary prospectus supplement on August 5, 2019 and a final prospectus supplement on August 7, 2019, both of which formed part of the Form S-3 registration statement filed by Allakos on August 5, 2019 and signed by Defendants Alexander and Redmond.

110. The August 5, 2019 ENIGMA Press Release, the August 5, 2019 preliminary prospectus supplement, and the August 7, 2019 final prospectus supplement all made the same statement that statistically significant results were achieved for patients in the ENIGMA Trial that did not receive steroids:

> **Steroid Use**
> ***Steroid use was balanced between drug and placebo groups. Statistically significant results were also observed on all primary and secondary endpoints in the subgroup of patients who did not receive steroids.***

(emphasis added).

111. On August 5, 2019, Allakos conducted the August 5, 2019 Conference Call and the Company issued a Form 8-K signed by Defendant Alexander on the same date with the August 5, 2019 Presentation attached. Defendants Alexander and Rasmussen used the August 5, 2019 Presentation during the August 5, 2019 Conference Call. The Form 8-K with the August 5, 2019 Presentation attached was incorporated by reference into the Form S-3 registration statement, signed by Defendants Alexander and Redmond, and filed by the Company on August 5, 2019.

112. On the August 5, 2019 Conference Call, Defendant Rasmussen stated that there was acute steroid use in only 28% of AK002 patients in the ENIGMA Trial and that there was compelling efficacy data for patients that were not given steroids:

> ***And again, as you can see here, the acute steroids use was well balanced between groups, 28% on AK002 versus 35% on placebo.*** But again, we --to test the robustness of the data, we did an analysis in which we excluded all patients who received steroids. And those analysis: Per protocol analysis, the patients excluding all steroid treatment and the ITT analysis are shown here. ***And as you can see, primary endpoint still met with very substantial p values, no matter what analysis you are looking at. The same was basically the case for the key secondary endpoints. So even looking at the ITT analysis or looking at analysis excluding all patients on steroids, we are getting the same compelling efficacy data, which is a testament to the robustness of the data in the study.***

(emphasis added).

113. During the August 5, 2019 Conference Call, Defendant Alexander stated that "steroids had absolutely 0 effect on the results" on the ENIGMA Trial: "***In terms of the steroid, I mean, it had absolutely 0 effect on the results, and that was shown in the study. So the idea that steroids are confounding the results is specious***." (emphasis added).

114. Slide 23 of the August 5, 2019 presentation stated that there was acute steroid use in only 28% of AK002 patients in the ENIGMA Trial :

> • **Acute steroid use across both groups:**
> – ***28% AK002, 35% placebo***

(emphasis added).

115. Slide 24 of the August 5, 2019 Presentation indicated that ***only 11 out of 39 members of the group that received AK002 and completed the ENIGMA Trial received any***

steroids at all.

116. The bold and italicized portions of the statements in Paragraphs 110 and 112-115 are false and misleading because Defendants significantly understated the number of patients in the ENIGMA Trial who received steroids. Additionally, the dosing of the steroids was inconsistent and left to the discretion of the trial investigators. Therefore, steroid use was a confounding factor in the ENIGMA Trial and Defendants' claims that the ENIGMA Trial showed that AK002 was effective regardless of steroid usage was misleading. By misrepresenting and/or failing to disclose these facts, Allakos misled investors about the integrity and quality of the ENIGMA Trial results and the likelihood that Allakos will be able to use the ENIGMA Trial to gain FDA approval of AK002.

D. Misstatements About Serious Adverse Events.

117. On August 5, 2019, Allakos issued a Form 8-K signed by Defendant Alexander with the August 5, 2019 ENIGMA Press Release.

118. Allakos filed a preliminary prospectus supplement on August 5, 2019 and a final prospectus supplement on August 7, 2019, both of which formed part of the Form S-3 registration statement filed by Allakos on August 5, 2019 and signed by Defendants Alexander and Redmond.

119. The August 5, 2019 ENIGMA Press Release, the August 5, 2019 preliminary prospectus supplement, and the August 7, 2019 final prospectus supplement all made the same statement that there was only "1 drug-related serious adverse event (SAE) in the study, consisting of an infusion-related reaction which recovered within 24 hours":

> **Safety**
> ***AK002 was generally well tolerated.*** The only treatment emergent adverse event occurring more frequently on AK002 than on placebo was mild to moderate infusion-related reactions (including flushing, feeling of warmth, headache, nausea, and/or dizziness) which occurred in 60% of AK002 treated patients and 23% of placebo treated patients. ***There was 1 drug-related serious adverse event (SAE) in the study, consisting of an infusion-related reaction which recovered within 24 hours.*** Treatment emergent SAEs occurred in 9% of patients on AK002 versus 14% on placebo

(emphasis added).

120. On August 5, 2019, Allakos conducted the August 5, 2019 Conference Call and the Company issued a Form 8-K signed by Defendant Alexander on the same date with the August 5,

2019 Presentation attached. Defendants Alexander and Rasmussen used the August 5, 2019 Presentation during the August 5, 2019 Conference Call. The Form 8-K with the August 5, 2019 Presentation attached was incorporated by reference into the Form S-3 registration statement, signed by Defendants Alexander and Redmond, and filed by the Company on August 5, 2019.

121. Defendant Rasmussen stated that there was only 1 drug-related serious adverse event during the ENIGMA Trial and it resolved within 24 hours during the August 5, 2019 Conference Call:

> ***We had 1 drug-related serious adverse event, an infusion reaction which recovered within 24 hours with no sequelae.*** If you look at the total number of treatment-emergent serious adverse event[s], the incident was 9% on AK002 versus 14% on placebo. ***And we didn't find any other significant adverse event. So worthwhile to mention here that there don't seem to be any adverse event outside the infusion windows.***

122. Slide 31 of the August 5, 2019 Presentation similarly stated that there was only one serious adverse event during the ENIGMA Trial that was resolved within 24 hours.

> • ***Generally well tolerated***
> • Most common AE was mild to moderate infusion related reactions (IRR)
> – 60% of AK002 patients vs 23% placebo
> – 93% mild to moderate (flushing, feeling of warmth, headache, nausea, dizziness)
> – Mostly on first infusion, greatly reduced or does not occur on subsequent infusions
> – ***1 drug-related serious adverse event, an IRR which recovered within 24 hours with no further sequelae***
> • Treatment-emergent SAEs: 9% on AK002, 14% on Placebo
> • ***No other significant AEs***

123. The bold and italicized portions of the statements in Paragraphs 119, 121-122 are false and misleading because patients in the ENIGMA Trial experienced more than 1 drug-related serious adverse event and some of those serious adverse events took more than 24 hours to resolve. By misrepresenting and/or failing to disclose these facts, Allakos misled investors about the safety of AK002 and the likelihood that Allakos will be able to use the ENIGMA Trial to gain FDA approval of AK002.

124. On the August 5, 2019 Conference Call, Defendant Rasmussen stated the following about the serious adverse events in the ENIGMA Trial:

> Yes. So in terms of serious adverse events. So they weren't in -- the 9% versus 14% where all treatment-emergent serious adverse event, and they were basically -- they're basically a combination of different things. This is a sick patient population who have a lot of problems. Many of them have a number of concomitant diseases. ***So typically, the serious adverse events were basically defined by a patient being hospitalized, in most cases, because of GI problems.*** And that's probably why the incidence was slightly higher on placebo as compared to on active.
>
> So we had a couple of patients who were hospitalized because of severe abdominal pain and/or dehydration, which of course, is a common problem with these patients. ***So nothing remarkable, but mostly GI-related.*** We did have one patient who had mental confusion, and turned out that she was on background drugs. So that kind of stuff.

125. On August 5, 2019, Allakos issued its 2Q 2019 10-Q, which was signed by Defendants Alexander and Redmond. Additionally, attached to the 2Q 2019 10-Q were certifications pursuant to SOX, signed by Defendants Alexander and Redmond, attesting that "this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" and that they have disclosed all fraud.

126. On November 12, 2019, Allakos filed the 3Q 2019 10-Q. Additionally, attached to the 3Q 2019 10-Q were certifications pursuant to SOX, signed by Defendants Alexander and Redmond, attesting that "this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" and that they have disclosed all fraud.

127. Regarding significant adverse events, the 2Q 2019 10-Q and 3Q 2019 10-Q stated:

> ***Our clinical trials may reveal significant adverse events, toxicities or other side effects and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.***

> In order to obtain marketing approval for any of our product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials, or have unexpected characteristics, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.
>
> …
>
> ***AK002 has generally been well tolerated in our clinical trials.*** The most common adverse event has been the occurrence of mild to moderate infusion-related reactions ("IRRs") (consisting of flushing, feeling of warmth, headache, nausea or dizziness) which occurred mostly, but not exclusively, during the first infusion. ***Temporal interruption of the AK002 infusion and minimal intervention generally resulted in prompt resolution of symptoms and ability to resume the infusion without further complications, although there have been instances when an IRR has resulted in a subject being discontinued from a trial***. ….
>
> If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, the EMA, other applicable regulatory authorities or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. ….

(emphasis in first three lines in original; other emphasis added).

128. The bold and italicized portions of the statements in Paragraph 124 and 127 are false and misleading because Defendants failed to disclose that patients in the ENIGMA Trial experienced multiple drug-related serious adverse events. By misrepresenting and/or failing to disclose these facts, Allakos misled investors about the safety of AK002 and the likelihood that Allakos will be able to use the ENIGMA Trial to gain FDA approval of AK002.

E. Misstatements About Vomiting During the ENIGMA Trial.

129. On August 5, 2019, Allakos conducted the August 5, 2019 Conference Call and the Company issued a Form 8-K signed by Defendant Alexander on the same date with the August 5, 2019 Presentation attached. Defendants Alexander and Rasmussen used the August 5, 2019 Presentation during the August 5, 2019 Conference Call. The Form 8-K with the August 5, 2019

Presentation attached was incorporated by reference into the Form S-3 registration statement, signed by Defendants Alexander and Redmond, and filed by the Company on August 5, 2019.

130. In the August 5, 2019 Presentation, Slide 20 shows a 100% improvement in the vomiting Patient Reported Outcome Symptom Score.

131. Slide 30 of the August 5, 2019 Presentation does not list vomiting as a treatment-emergent adverse effect of AK002.

132. During the August 5, 2019 Conference Call, Defendant Alexander stated that vomiting was "neither frequent nor severe" during the ENIGMA Trial:

> And I think as we had guided folks over the last couple of months, that vomiting in particular, and then diarrhea also, were 2 symptoms that were not as frequent as the others and were not as severe. And in the case of vomiting, it was neither frequent nor severe.

133. The statements in Paragraphs 130-132 are false and misleading because at least four patients in the ENIGMA Trial experienced vomiting that worsened after they entered the ENIGMA Trial. By misrepresenting and/or failing to disclose these facts, Allakos misled investors about the likelihood that Allakos will be able to use the ENIGMA Trial to gain FDA approval of AK002.

LOSS CAUSATION

134. On December 18, 2019, Seligman Investments published the Seligman Report.

135. On this news, shares of Allakos fell $22.73 per share over two days, or more than 17% from the closing price on December 17, 2019 to close at $109.80 on December 19, 2019, damaging investors.

136. As a result of Defendants' wrongful acts and omissions, Plaintiffs and other Class members have suffered significant losses and damages.

ADDITIONAL SCIENTER ALLEGATIONS

A. Defendants Were Motivated to Make False and Misleading Statements Because Allakos Could Not Continue its Operations or Drug Development Unless it Raised Additional Capital.

137. Allakos admitted in its 2018 10-K, 1Q 2019 10-Q, and 2Q 2019 10-Q that it could not continue its operations if it did not raise additional capital and would have to delay, reduce, or

terminate its development efforts: "We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future" and "if we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development and commercialization efforts."

138. On August 5, 2019, Allakos announced the results from the ENIGMA Trial. The ENIGMA Trial was the most important trial in Allakos' history since AK002 is the Company's only clinical stage drug and EG and EGE are Allakos' lead indications for AK002. Additionally, Defendant Alexander stated during the August 5, 2019 Conference Call that Allakos intended to use the ENIGMA Trial as one of two clinical trials necessary for FDA approval of AK002. As detailed above, Defendants' announcement of the ENIGMA Trial's results contained numerous material misstatements that misled investors about the about the integrity and quality of the ENIGMA Trial results and the likelihood that Allakos will be able to use the ENIGMA Trial to gain FDA approval of AK002.

139. Mere hours after announcing the results of the ENGIMA Trial, and making numerous material misstatements, Allakos announced a secondary public offering of $200 shares of its common stock, the Company's first public offering of common stock since its IPO. The preliminary prospectus supplement, filed on August 5, 2019 and final prospectus supplement for that offering, filed on August 7, 2019, continued to make material misstatements about the ENIGMA Trial.

140. After Defendants' misstatements caused Allakos' share price to dramatically increase, Allakos announced it was upsizing its secondary offering of common stock to $350 million at an offering price of $77 per share. On August 9, 2019, the Company announced that it had raised $377.5 million.

141. Given that Allakos admitted that it could not continue its operations and would likely have reduce, terminate or delay development of AK002 if it could not raise money, Defendants were highly motivated and had the opportunity to make material misstatements about the ENIGMA Trial.

B. Allakos Purportedly Granted Defendant Redmond 120,000 Stock Options One Business Day Prior to Making Misstatements About the ENIGMA Trial and Did Not Reveal the Options Grant Until it was Worth Almost $6 Million.

142. Allakos' stock closed at $31 on Friday, August 2, 2019. After Defendants announced the results of the ENIGMA Trial, and made numerous material misstatements, the stock price shot up dramatically and closed at $79.47 on August 6, 2019.

143. On August 6, 2019, Allakos filed a Form 4 that stated it had granted 120,000 stock options to Defendant Redmond ***on August 2, 2019 at the price of $31.*** When Allakos announced Defendant Redmond's stock options, they were already worth almost $6 million.

C. Defendants Behaved Intentionally or Recklessly When They Made Misstatements.

144. Given the importance of the ENIGMA Trial to the future of Allakos and the small size of the Company, it is inconceivable that Defendant Alexander, as CEO, would not be aware or have access to information about the aspects of the ENIGMA Trial that he made misrepresentations about including, Allakos' failure to use a CRO, the Trial's poor blinding controls, steroid use during the Trial, serious adverse events during the Trial, and vomiting during the Trial. Additionally, because of his Ph.D. in immunology and his previous experience as CEO of another pharmaceutical company, Defendant Alexander well understood the significance of these issues as to Good Clinical Practice and how they affect the reliability, integrity, and quality of the trial results. Furthermore, Defendant Alexander spoke knowledgably about the ENIGMA Trial during the August 5, 2019 Conference Call and represented that it would be one of two clinical trials used in Allakos' application to the FDA for approval of AK002 for EG and EGE patients. Allakos' 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, and 3Q 2019 10-Q all warn that the Company is "highly dependent" on Defendant Alexander.

145. Given the importance of the ENIGMA Trial to the future of Allakos and the small size of the Company, it is inconceivable that Defendants Redmond and Tomasi as CFOs during various points during the Class Period, and therefore the principal financial officer of the Company, would not be aware or have access to the information that Allakos failed to use a CRO for the ENIGMA Trial. Defendants Redmond and Tomasi also would have been aware of or have access to information about the poor blinding controls during the ENIGMA Trial, steroid use during the Trial,

serious adverse events during the Trial, and vomiting during the Trial. Additionally, because of Defendant Tomasi's Ph.D. in chemistry and his previous experience as Chief Scientific Officer of another pharmaceutical company and Defendant Redmond's experience as President of another pharmaceutical company, Defendants Tomasi and Redmond well understood the significance of these issues as to Good Clinical Practice and how they affect the reliability, integrity, and quality of the trial results. Defendant Tomasi also served as the Company's President and COO during the class period and Allakos' 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, and 3Q 2019 10-Q all warn that the Company is "highly dependent" on Defendant Tomasi.

146. Defendants Alexander, Redmond, and Tomasi were provided with copies of Company's SEC filings that they signed that contained misleading statements alleged herein before their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected.

147. Defendant Alexander was, at minimum, reckless when he authorized the issuance and signed the 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, 3Q 2019 10-Q, the August 5, 2019 8-Ks with the August 5, 2019 ENGIMA Trial Press Release and the August 5, 2019 Presentation attached, and the August 5, 2019 S-3 registration statement which incorporated the August 5, 2019 preliminary prospectus supplement and August 7, 2019 final prospectus supplement. Defendant Alexander was also, at minimum, reckless when he signed the SOX certifications that accompanied the 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, 3Q 2019 10-Q. He was also, at minimum, reckless when he made misstatements about he ENIGMA Trial on the August 5, 2019 Conference Call.

148. Defendant Redmond was, at minimum, reckless when he authorized the issuance and signed the 2Q 2019 10-Q, 3Q 2019 10-Q, and the August 5, 2019 S-3 registration statement. The August 5, 2019 S-3 Registration Statement incorporated the August 5, 2019 preliminary prospectus supplement, the August 7, 2019 final prospectus supplement, the August 5, 2019 8-Ks with the August 5, 2019 ENGIMA Trial Press Release and the August 5, 2019 Presentation attached, the 2018 10-K, and the 1Q 2019 10-Q. Defendant Redmond was also, at minimum, reckless when he signed the SOX certifications that accompanied the 2Q 2019 10-Q and 3Q 2019 10-Q.

149. Defendant Tobias was, at minimum, reckless when he signed and authorized the

issuance of the 2018 10-K and 1Q 2019 10-Q and when he signed the SOX certificates associated with those filings.

150. Given the importance of the ENIGMA Trial to the future of Allakos and the small size of the Company, it is inconceivable that Defendant Rasmussen, as CMO would not be aware or have access to information about the aspects of the ENIGMA Trial that he made misrepresentations about including, Allakos' failure to use a CRO, the Trial's poor blinding controls, steroid use during the Trial, serious adverse events during the Trial, and vomiting during the Trial. Furthermore, Defendant Rasmussen spoke to investors on the August 5, 2019 Conference Call specifically because he was knowledgeable about the ENIGMA Trial and he demonstrated his knowledge of the ENIGMA Trial on that call. Furthermore, Defendant Rasmussen was knowledgeable about the ENIGMA Trial because he is the top clinical officer at Allakos and the Company conducted the Trial without a CRO. He was so intimately involved in the Trial that he improperly spoke to the relative of a patient in the Trial. Additionally, because of his Ph.D. and M.D. and his previous experience in high level clinical positions at other pharmaceutical companies, Defendant Rasmussen well understood the significance of the issues discussed above as to Good Clinical Practice and how they affect the reliability, integrity, and quality of the trial results. Accordingly, Defendant Rasmussen was, at minimum, reckless when he made misstatements on the August 5, 2019 Conference Call and when he authorized the issuance of and used the August 5, 2019 Presentation on that call.

D. There is a Strong Inference Allakos Acted With Scienter.

151. Each of the Individual Defendants was a high-ranking management-level employee. The scienter of each of the Individual Defendants and of all other management-level employees of Allakos, including each high-ranking officer or director, is imputable to the Company. The knowledge of each of these individuals should therefore be imputed to Allakos for the purposes of assessing corporate scienter.

152. The facts alleged herein raise a strong inference of corporate scienter as to Allakos as an entity. Corporate scienter may be alleged independent of the finding that any Individual Defendant had scienter where a statement is made or approved by a corporate official sufficiently

knowledgeable about the company to know the statement was false or misleading. Given the importance of the ENIGMA Trial to Allakos, the false and misleading statements alleged in this complaint would necessarily have required the approval of a corporate officer with knowledge that they were false and misleading.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

153. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased Allakos common stock during the Class Period, held it until the end of the Class Period, and were damaged upon the revelation of the alleged corrective disclosures (the "Class"). Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

154. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Allakos common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

155. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

156. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

157. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Individual Defendants caused the Company to issue false and misleading SEC filings and public statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;
- whether the prices of Allakos common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

158. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

159. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;
- Allakos common stock are traded in an efficient market;
- the Company's common stock were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and
- Plaintiffs and members of the Class purchased and/or sold Allakos common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

160. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

161. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in Affiliated *Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Against All Defendants

162. Plaintiffs repeat and realleges each and every allegation contained above as if fully set forth herein.

163. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

164. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained

misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

165. The Company and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Allakos common stock during the Class Period.

166. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

167. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiffs and the Class.

168. As a result of the foregoing, the market price of Allakos common stock was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiffs and the other members of the Class relied on the statements described above and/or the integrity of the market price of Allakos common stock during the Class Period in purchasing Allakos common stock at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

169. Had Plaintiffs and the other members of the Class been aware that the market price of Allakos common stock had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company's and the Individual Defendants did not disclose, they would not have purchased Allakos common stock at the artificially inflated prices that they did, or at all.

170. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of the Class have suffered damages in an amount to be established at trial.

171. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of Allakos common stock during the Class Period.

COUNT II

Violation of Section 20(a) of The Exchange Act Against The Individual Defendants

172. Plaintiffs repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

173. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

174. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial

condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

175. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Allakos common stock.

176. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

177. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: August 28, 2020

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

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